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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/568,432	02/14/2006	Andrew Cassidy	056291-5231	2301
9629 7590 12/11/2008 MORGAN LEWIS & BOCKIUS LLP 1111 PENNSYLVANIA AVENUE NW WASHINGTON, DC 20004				
EXAMINER BAUGHMAN, MOLLY E				
ART UNIT		PAPER NUMBER		
1637				
MAIL DATE		DELIVERY MODE		
12/11/2008		PAPER		

**Please find below and/or attached an Office communication concerning this application or proceeding.**

The time period for reply, if any, is set in the attached communication.

### Office Action Summary

**Application No.**

10/568,432

**Applicant(s)**

CASSIDY ET AL.

**Examiner**

Molly E. Baughman

**Art Unit**

1637

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --  
**Period for Reply**

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

**Status**

- 1) ☒ Responsive to communication(s) filed on 28 August 2008.
- 2a) ☒ This action is **FINAL**. 2b) ☐ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

**Disposition of Claims**

- 4) ☒ Claim(s) 56-64, 66 and 88-108 is/are pending in the application.
- 4a) Of the above claim(s) 88-108 is/are withdrawn from consideration.
- 5) ☐ Claim(s) \_\_\_\_\_ is/are allowed.
- 6) ☒ Claim(s) 56-64 and 66 is/are rejected.
- 7) ☐ Claim(s) \_\_\_\_\_ is/are objected to.
- 8) ☐ Claim(s) \_\_\_\_\_ are subject to restriction and/or election requirement.

**Application Papers**

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on \_\_\_\_\_ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.  
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).  
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

**Priority under 35 U.S.C. § 119**

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some \* c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
  2. ☐ Certified copies of the priority documents have been received in Application No. \_\_\_\_\_.
  3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

\* See the attached detailed Office action for a list of the certified copies not received.

**Attachment(s)**

- 1) ☐ Notice of References Cited (PTO-892)
- 2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
- 3) ☐ Information Disclosure Statement(s) (PTO/SF-08)  
Paper No(s)/Mail Date \_\_\_\_\_
- 4) ☐ Interview Summary (PTO-413)  
Paper No(s)/Mail Date \_\_\_\_\_
- 5) ☐ Notice of Informal Patent Application
- 6) ☐ Other: \_\_\_\_\_

#### **DETAILED ACTION**

1. Claims 1-44, and 67-87 were previously cancelled. Applicant's amendments to claims 56-62, 64, and 66; cancellation of claim 65; and addition of claims 88-108 in the reply filed on 5/19/08 are acknowledged.
2. Applicant's corrected claim identifiers for new claims 88-108, particularly, clarifying that the new claims are "new, withdrawn" claims, in the reply filed on 8/28/08 is acknowledged and accepted.
3. Applicant's amendments to the specification in the reply filed on 5/19/08, particularly, claiming priority to PCT/GB2004/003486 is acknowledged and accepted.
4. Claims 56-64, and 66 are currently under examination.

#### ***Response to Arguments***

5. Applicant's arguments, see pg.11, filed 5/19/08, with respect to rejection of claims 56-66 under 35 U.S.C. 112, second paragraph, have been fully considered and are persuasive. The rejection of claims 56-66 has been withdrawn.
6. Applicant's arguments, see pg.11-12, filed 5/19/08, with respect to rejection of claims 56-66 (now claims 56-64 and 66) under 35 U.S.C. 103(a) (Zhu et al. (US 6,465,219) in view of Chenchik et al., (1998), "Generation and Use of High-Quality cDNA from Small Amounts of Total RNA by SMART PCR," Natick, MA: BioTechniques Books (of record), *or* Petalidis et al., "Global amplification of mRNA by template-switching PCR: linearity and application to microarray analysis," Nucleic Acids

Research, Nov. 2003, Vol.31, No.22, e142, pp.1-7, *or* Chenchik et al. (US 5,962,272)), have been fully considered but they are not found persuasive.

Applicants first argued that Zhu does not disclose or suggest a cDNA-mRNA hybrid containing an amplifier sequence and a template switching oligonucleotide (TSO) having the same sequence to allow amplification using a single amplification primer, and none of Chenchik 1, Petalidis, or Chenchik 2 teach a cDNA-mRNA hybrid for generating antisense RNA molecules using a RNA promoter that is recognized by a bacteriophage RNA polymerase, such as the T7 polymerase. In response to applicant's arguments against the references individually, one cannot show nonobviousness by attacking references individually where the rejections are based on combinations of references. See *In re Keller*, 642 F.2d 413, 208 USPQ 871 (CCPA 1981); *In re Merck & Co.*, 800 F.2d 1091, 231 USPQ 375 (Fed. Cir. 1986).

Applicant's further argued that there would be no reason to combine Zhu with Chenchik 1, Petalidis, or Chenchik 2 since Zhu discloses using the cDNA-mRNA hybrid for generating RNA molecules and each of Chenchik 1, Petalidis, and Chenchik 2 teach using their cDNA-mRNA hybrid for generating double-stranded cDNA molecules. In response, one cannot show nonobviousness by attacking references individually where the rejections are based on combinations of references. See *In re Keller*, 642 F.2d 413, 208 USPQ 871 (CCPA 1981); *In re Merck & Co.*, 800 F.2d 1091, 231 USPQ 375 (Fed. Cir. 1986). Furthermore, the examiner provided a reason to combine in the previous Office Action, dated 12/17/07, where she stated:

*Zhu et al. demonstrates the need for incorporating sequences into the cDNA-RNA hybrid that can be used for later amplification, as he notes that the universal primer site (i.e. complementary sequence to the TSO) and the antisense primer complex sequence can serve "as anchors for efficient and sufficiently specific PCR amplification" (col.13, lines 19-25). Chenchik 1, Petalidis, and Chenchik 2 all demonstrate that it was conventional in the art at the time of the invention to incorporate amplifier sequences 5' to the RNA annealing region of the cDNA strand, which contain the same sequence as the TSO sequence and can be used in supplemental amplification using a single primer. Furthermore, Chenchik 1 states that attaching an arbitrary sequence to the 5' end of the cDNA by priming in order to create universal primer binding sites is more efficient and less complex than other methods, including adaptor ligation or homopolymer tailing, and allows such sequences to be incorporated in a single step, in a single tube and within an hour (see pg.306, second and third paragraphs; pg.313, second paragraph; pg.318, "Advantages and Limitations of the SMART Technology," first paragraph). Since Zhu et al. demonstrates the benefits of incorporating sequences into the cDNA-RNA hybrid that can be used for later amplification and Chenchik 1, Petalidis, and Chenchik 2 all demonstrate that it was conventional in the art at the time of the invention to incorporate amplifier sequences 5' to the RNA annealing region of the cDNA strand, which contain the same sequence as the TSO sequence and can be used in supplemental amplification using a single primer, it would have been obvious to one skilled in the art to add an amplifier sequence, containing the same sequence as the TSO sequence, 5' to the RNA polymerase*

*promoter sequence to achieve the predictable result of incorporating sequences into the cDNA-RNA hybrid that can be used for later amplification.*

Therefore, in the absence of secondary considerations, the rejection is maintained.

### ***Summary***

7. No claims are free of the prior art.
8. Any remaining rejections and/or objections not addressed above are withdrawn in view of the amendments and/or arguments.

### ***Conclusion***

9. **THIS ACTION IS MADE FINAL.** Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

A shortened statutory period for reply to this final action is set to expire THREE MONTHS from the mailing date of this action. In the event a first reply is filed within TWO MONTHS of the mailing date of this final action and the advisory action is not mailed until after the end of the THREE-MONTH shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of the advisory action. In no event, however, will the statutory period for reply expire later than SIX MONTHS from the mailing date of this final action.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Molly E. Baughman whose telephone number is (571)272-4434. The examiner can normally be reached on Monday-Friday 8-5pm.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Gary Benzion can be reached on 571-272-0782. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.

/Kenneth R Horlick/  
Primary Examiner, Art Unit 1637

/Molly E Baughman/  
Examiner, Art Unit 1637